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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/735.362	12/12/2003	Diana J. Parsons	parsons 3	1804
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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,362	PARSONS, DIANA J.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-37 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in the view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below. The instant claims are not enabled to prevent healing of the skin indefinitely and the process of treatment by prevention of healing.

Nature of the Invention: The rejected claims are drawn to the method of *treating* the skin comprising: a) pre-treating the skin with a topical collagen-promoting agent; b) producing a wound in the high dermis of the skin; treating the skin chronically with said topical collagen-promoting agent after producing said wound in the high dermis; and d) maintaining the high dermis in a chronically wounded condition through a plurality of wounding events, preventing

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the wound from healing. Summarily, the instant invention is directed to a method of treating the skin wherein the skin is wounded and preventing the skin from healing indefinitely.

Breath of the claims: The breadth of the claim encompasses preventing the inherent defense mechanism of the human body indefinitely in a methodology directed to treatment. The scope also encompasses providing treatment by damaging the skin. The contradiction of “treating” by inducing wounds is noted; i.e. the methodology is in direct contradiction of the method steps.

Guidance of the Specification: The guidance provided by the specification on page 9 and 10 instructs a skilled artisan to initially wound the skin using a laser and to chronically wound the skin by repeating the laser treatment at least 6 times in 6 months and subsequently on an yearly basis. Page 5 of the instant specification states that in the “first five days the wound is comprised of inflammatory cells and new blood vessels. Then an immature form of collagen is laid down parallel to the skin surface”. As acknowledged by applicant, the process of healing occurs at the latest, in five days, and the specification only provides guidance on preventing healing indefinitely by wounding the skin 6 times in a span of 6 months and on a yearly basis. The specification does not speak on the immune system or suppression of the immune system to prevent skin healing, which is a vital in the prevention of healing. The specification does not provide guidance on step (d). Moreover, page 1 of the instant specification discloses that prior art laser treatments cause severe burns (burns are considered wounds) which leads to infection, scarring, and pigmentation. Thus, the specification discloses that wounding the skin and preventing if healing does not treat the skin rather it causes more complications.

The State of the Art: Firstly, the state of the art recognizes that the immune system immediately responds after trauma such as a wound. The examiner cites Gryglewski, et al, Immunological aspects of trauma, Postepy Heg Med Dosw, 2006; 60:192-200. Gryglewski disclose that in response to trauma, repair and defense mechanisms, involved in tissue repair, wound healing, and prevention of infection, are induced. Gryglewski discloses that the magnitude of the trauma-induced response depends on the patient's overall condition and the severity of the injury. Gryglewski discloses minor injury usually elicits a local reaction, while severe trauma is associated with a systemic host response. Gryglewski discloses severe trauma generally causes suppression of the immune system. The examiner further cites <http://www.healthynj.org/dis-con/burns/main.htm>, which discloses first and second degree burns heal in days to weeks without scarring; deep second degree burns and small third degree burns take weeks to heal and scar, and large third degree burns require skin grafting and may be fatal. HealthyNJ further discloses that severe burns take a long time to heal, sometimes years, and cause disfigurement. Thus, as evidenced by the state of the art, the prevention of skin healing indefinitely requires either 1) the suppression of the immune system (which is not discussed in the specification) or 2) damage so severe that impairs bodily function and causes disfigurement. With regard to the latter, causing a wound that severely damages the skin, which in turn impairs the immune system and other bodily functions, contradicts the methodology of "treating" and in actuality prevents "treatment" from occurring.

The examiner cites Mousa, Burn and Scald Injuries, East Mediterranean Health Journal, 2005 Sep-Nov; 11(5-6):1099-109. Mousa discloses that infections is the major cause of morbidity and mortality in burns. Thus, Mousa discloses aggressive treatment include early

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wound closure improves mortality rates of burn patients. Page 1 of the instant specification concurs that the lack of healing causes complications such as infections. Thus, the state of the art recognizes that the process of healing is fundamental to the treatment of skin and the lack of healing leads to complication including life-threatening infections. Therefore, one cannot attempt to *treat* by preventing wound healing.

Lastly, the examiner cites US 6,050,990, which is directed to laser treatment. Tankovich discloses the importance of preventing burning of the skin, damaging blood vessels, destroying the skin pigmentation, i.e., the melanosomes. The state of the art, i.e. laser treatment, recognizes that the purpose of treatment with lasers is not to damage the skin as currently claimed.

Working Examples: The specification does not contain working examples.

Predictability of the Art: The lack of significant guidance from the specification or the prior art with regard to the actual prevention of skin healing indefinitely by only wounding the skin on a yearly basis and the treatment of the skin by chronically wounding, makes practicing the instant invention unpredictable.

The Amount of experimentation Necessary: In order to practice the claimed invention, a skilled artisan would have to predict what type of wound, how long the damage needs to be inflicted, etc. to sufficiently impair the immune system to prevent healing. If unsuccessful, which is likely given the lack of guidance from the specification and prior art, a skilled artisan would have to then envision a modification of the first experiment or envision an entirely new experiment, and test the process again. This process would be repeated until successful and therefore it would require undue and unpredictable experimentation to practice the claimed scope.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims 1 and 21 are directed to preventing wound healing from occurring which is vague and indefinite. It is unclear what the metes and bounds of this step are and how one would indefinitely prevent healing in a methodology directed to healing.

Independent claim 1 requires the application of a “topical collagen promoting agent”. Dependent claim 2 requires the further use of a blood-promoting agent. Dependent claim 3 defines the collagen-promoting agent as retinoic acid and claim 4 defines the blood vessel promoting agents as retinoic acid. Although it is noted that claim 4 does not depend on claim 3, it is noted that the specification only discloses the use of retinoic acid as the collagen promoting agent and blood vessel promoting agent. Therefore, retinoic acid acts as both. Thus, it is unclear how the composition can further comprise a blood vessel promoting agent, which is the same agent as claimed in the independent claim.

Claim 6 and 22 recite “wherein said production of a chronic wound in the high dermis leaves the epidermis intact” which is vague and indefinite. This is unclear since the epidermis is the outermost layer and the dermis supports and strengthens the epidermis. Therefore, it is unclear how the dermis is wounded without the epidermis being wounded since the dermis lies below the epidermis. Further clarification is requested.

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Claim 29 recites, “said laser light has a wave length of about 1064 nM”. However, claim 29 depends from claim 28, which recites “a wave length of from about 800 nM to 1000 nM.”

Claim 29 is indefinite since it is a broader claim than its parent claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 11, 14-16, 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883).

Kye YC discloses a method of resurfacing pitted facial scars including acne scars, chicken pox scar, and small pox scars, with a pulsed Er:YAG laser. The method includes: step (a) prior to laser surgery, the patients are treated with 0.05% tretinoin (note 0.05% reads on about 0.1%) nightly for two to four weeks; step (b) the patient is then treated with Er:YAG laser at a setting of 500mJ/pulse and 3.5-4.5 Watts with a pulse frequency of 7-9 Hz. Kye discloses that after 4-6 laser passes, pinpoint bleeding occurred; step (c) two weeks after laser treatment % tretinoin and 1% hydrocortisone cream is applied for 2-4 weeks. See abstract. Note that step (d) is induced by the use of tretinoin itself which causes chronic skin irritation and peeling, which reads on the broad recitation of “maintaining the high dermis is a wounded state”.

Claims 1-4, 11, 14-16, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7).

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Ho et al disclose laser resurfacing in pigmented skin and skin with acne scars with a CO₂ laser. The method includes: step (a) The patients were treated with 0.05% tretinoin (note 0.05% reads on about 0.1%) , 5% hydroquinone, and 0.1% desonide cream nightly for 2-4 weeks prior to the laser treatment (b) The Ultrapulse 5000C CO₂ laser with a setting of 250-450 mJ per pulse, or the Silk-Touch flashscanner at the setting of 5-7 W, 0.2-second pulse duration, and 4-mm (M) spot size, is used on the skin; (c) tretinoin, hydroquinone, and desonide and broad spectrum sunscreen is also used postoperatively. Note that step (d) is induced by the use of tretinoin itself which causes chronic skin irritation and peeling, which reads on the broad recitation of “maintaining the high dermis is a wounded state”.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10, 14-16, 19-23, 26-29, 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al (6,050,990) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7).

Tankovich teaches a method of hair removal and skin treatment including treating herpes virus lesions and infections, treating scar tissue, and skin rejuvenation (see column 52, lines 10-30) utilizing laser therapy. See abstract. The procedure entails utilizing a contaminant such as a

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suspension of carbon particles in an oil- or water-based medium and illuminating the skin with laser pulses. A Q-switched Nd:YAG laser with a wavelength of 1064 nm is utilized in the process.

The method used for treating scars includes: applying a contaminant to keloid or hypertrophic scar tissue, and the area is irradiated by laser energy for about 5 or 6 passes, or until erythema or minor inflammation is detected in the scarred area. Then a period of about 4 to about 6 weeks is allowed to pass before the treatment is repeated. A total of from about 2 to about 8 treatments is generally sufficient to cause reorganization of the epithelial layer and removal of the scar. See column 58.

The parameters for treating the skin for hair removal includes using a Nd:YAG laser with a pulse frequency of 10 Hertz (10 pulses per second) and a fluence of about 2 to 3 J/cm². see column 12, lines 45-20 and column 34, lines 5-20. The pulse frequency may be a combination of both short pulses (10 ns to about 30ns) and long pulses (100 microseconds to 100ms).

Tankovich teaches the instant fluence of about 2.5 J/cm² and a pulse duration of 10ns (0.01 microsecond). See column 30, lines 45-51 and column 49, lines 5-10 . The treatment should be scheduled every 2 to 3 weeks after the hair follicle has fallen out. See column 48, lines 34-55.

The parameters for treating Herpes infections include wavelength of 1064nm, fluence of 1-2 J/cm², and a pulse energy of 0.5 J/pulse. See column 45, lines 1-10 and column 43, lines 25-40.

Tankovich teaches post-operative treatment of the targeted area includes any commonly accepted methods known to those in the medical arts.

Tankovich does not teach the instant pre-treatment or specify the post-treatment.

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Ho et al disclose laser resurfacing in pigmented skin and skin with acne scars with a CO2 laser. The method includes: (a) The patients were treated with 0.05% tretinoin, hydroquinone, and desonide cream nightly for 2-4 weeks prior to the laser treatment (b) The Ultrapulse 5000C CO2 laser with a setting of 250-450 mJ per pulse, or the Silk-Touch flashscanner at the setting of 5-7 W, 0.2-second pulse duration, and 4-mm (M) spot size, is used on the skin; (c) tretinoin, hydroquinone, and desonide and broad spectrum sunscreen is also used postoperatively. Ho discloses the reduction of hyperpigmentation with regular use of tretinoin, hydroquinone, and desonide cream both pre- and postoperatively along with use of broad-spectrum sunscreen after treatments. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made of Tankovich and Ho et al and utilize a pre-treatment and post-treatment regimen prior to the laser therapy taught in Tankovich. One would have been motivated to do so since Ho teaches the reduction of hyperpigmentation after laser resurfacing is reduced with regular use of tretinoin, hydroquinone, and desonide cream, both pre- and postoperatively. Furthermore, a skilled artisan would have expected similar results and success in using Ho's' pre/post treatment step in Tankovich's laser therapy since Tankovich teaches the laser therapy to treat skin disorders such as scars and teaches the use of any post treatment known in the art. Therefore, a skilled artisan would have been motivated to utilize a pre and post treatment step to reduce hyperpigmentation.

Note with regard to claim 8 and claim 21, Tankovich teaches repeating the laser process until sufficient results are obtained with regard to scars and Tankovich teaches repeating the laser process every two to three weeks for hair removal. Therefore, it is within the skill of an artisan to

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repeat laser therapy based on the desired result and maintenance for a certain cosmetic condition. For instance, with regard to hair removal, a skilled artisan would be motivated to maintain the treatment as long as required to maintain hair-free skin including at least once every twelve months or more depending on the hair growth pattern. With regard to skin rejuvenation taught by Tankovich, a skilled artisan would be motivated to maintain the treatment as long as required to maintain healthy and young skin including at least once every twelve months or more.

Claims 11-13 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al (6,050,990) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) in further view of Tadaki et al (The effect of topical tretinoin on the photodamaged skin of the Japanese, J. Exp. Med. 1993 Feb; 169(2): 131-9).

The teachings of Tankovich and Ho have been delineated above. HO teaches the application of tretinoin 2-4 weeks prior to the laser treatment and also post treatment.

The references do not teach reduced application of retinoic acid.

Tadaki teaches the use of retinoic acid as used for various purposes including excess pigmentation, sun damage, wrinkles, etc. Tadaki teaches the effectiveness of 0.1% tretinoin cream but it causes severe skin irritation in Japanese patients compared to Caucasian patients. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to Tadaki and reduce the application of tretinoin cream. One would have been motivated to do so since Tadaki teaches although tretinoin is effective in treating skin damage, it causes irritation and severity depends on the patient. Thus, the application of retinoic acid in the pre or post treatment depends on patient parameters including the skin type, condition of the

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skin, and skin color. For instance, a skilled artisan would have been motivated to reduce application of retinoic acid as taught by Ho, if the patient experienced severe irritation. For post-treatment a skilled artisan would have been motivated to utilize less retinoic acid applications if post-laser pigmentation was not severe or if skin irritation was severe.

Claims 17-18 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al (6,050,990) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) in view of Obagi (4,874,361).

The teachings of Tankovich and Ho have been delineated above.

The references do not specify the length of the laser treatment.

Obagi discloses a method of treating chronic skin problems (acne, wrinkles, pigmentation disorders) with laser treatment. Patients are treated with a composition that stimulate skin regeneration. After the composition is applied, the area is treated with light. The parameters chosen are dependent on the skin type (dark versus light), the type of peel (light versus deep), and severity of the skin condition. See column 5. However, usually the time range is 2-15 minutes with repeated treatments. See examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Tankovich et al, Ho et al, and Obagi and manipulate the length of the laser treatment. provide laser treatment for the instant parameters. One would be motivated to do so since Obagi discloses that the length of treatment depends on several factors including skin color and type and severity of the condition but the time can only be in the order of minutes regardless of race. Therefore, the length of treatment is a manipulatable parameter which depends on the various factors, including the severity of the condition, skin type and color,

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and the area treated and Obagi discloses that it is within the skill of an ordinary artisan to manipulate this parameter (column 5).

Conclusion

All the claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharmila S. Gollamudi
Examiner
Art Unit 1616